

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

IN RE APPLICATION OF: Michael R JOHNSON

SERIAL NO: NEW APPLICATION

FILED: HEREWITH

FOR: SODIUM CHANNEL BLOCKERS

**INFORMATION DISCLOSURE STATEMENT UNDER 37 CFR 1.97**

COMMISSIONER FOR PATENTS  
ALEXANDRIA, VIRGINIA 22313

SIR:

Applicant(s) wish to disclose the following information.

**REFERENCES**

- ☒ The applicant(s) wish to make of record the references listed on the attached Form PTO-1449 from prior U.S. Application Serial No. 10/076,571, filed February 19, 2002. Copies of the listed references are attached, where required, as are either statements of relevancy or any readily available English translations of pertinent portions of any non-English language references.
- ☐ A check or credit card payment form is attached in the amount required under 37 CFR §1.17(p).

**RELATED CASES**

- ☐ Attached is a list of applicant's pending application(s) or issued patent(s) which may be related to the present application. A copy of the patent(s), together with a copy of the claims and drawings of the pending application(s) is attached along with PTO 1449.
- ☐ A check or credit card payment form is attached in the amount required under 37 CFR §1.17(p).

**CERTIFICATION**

- ☐ Each item of information contained in this information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this statement.
- ☐ No item of information contained in this information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application or, to the knowledge of the undersigned, having made reasonable inquiry, was known to any individual designated in 37 CFR §1.56(c) more than three months prior to the filing of this statement.

**DEPOSIT ACCOUNT**

- ☒ Please charge any additional fees for the papers being filed herewith and for which no check or credit card payment is enclosed herewith, or credit any overpayment to deposit account number 15-0030. A duplicate copy of this sheet is enclosed.

Respectfully submitted,

OBLON, SPIVAK, McCLELLAND,  
MAIER & NEUSTADT, P.C.

  
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James J. Kelly  
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Form PTO 1449 (Modified)		U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE		ATTY DOCKET NO. 251513US96		SERIAL NO. NEW APPLICATION	
LIST OF REFERENCES CITED BY APPLICANT				APPLICANT Michael R. JOHNSON			
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<b>U.S. PATENT DOCUMENTS</b>							
EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB CLASS	FILING DATE IF APPROPRIATE
	AA	4,177,285	12-04-79	Cragoe, Jr. et al.			
	AB	3,794,734	02-26-74	Cragoe, Jr. et al.			
	AC	3,864,401	02-04-75	Schultz et al.			
	AD	3,914,253	10-21-75	Cragoe, Jr. et al.			
	AE	3,929,872	12-30-75	Cragoe, Jr. et al.			
	AF	3,931,239	01-06-76	Cragoe, Jr. et al.			
	AG	3,953,476	04-27-76	Cragoe, Jr. et al.			
	AH	3,966,966	06-29-76	Cragoe, Jr. et al.			
	AI	4,006,180	02-01-77	Cragoe, Jr. et al.			
	AJ	4,012,524	03-15-77	Cragoe, Jr. et al.			
	AK	4,159,279	06-26-79	Smith et al.			
	AL	4,163,781	08-07-79	Cragoe, Jr. et al.			
	AM	4,163,794	08-07-79	Cragoe, Jr. et al.			
	AN	4,085,219	04-18-78	Cragoe, Jr. et al.			
<b>FOREIGN PATENT DOCUMENTS</b>							
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<b>OTHER REFERENCES (Including Author, Title, Date, Pertinent Pages, etc.)</b>							
	AW	R. Tarran et al., <u>The CF Salt Controversy: In Vivo Observations and Therapeutic Approaches</u> , <i>Molecular Cell</i> , Vol. 8, 149-158, July 2001.					
	AX	Michael R. Knowles et al., <u>Amiloride in Cystic Fibrosis: Safety, Pharmacokinetics, and Efficacy in the Treatment of Pulmonary Disease</u> , Chapter 20, page 301-316.					
	AY	Louis Simchowitz et al., <u>An Overview of the Structure Activity Relations in the Amiloride Series</u> , Chapter 2, page 9-25.					
	AZ	J.R. Sabater et al., <u>Aerosolization of P2y2-Receptor Agonists Enhances Mucociliary Clearance in Sheep</u> , <i>The American Physiological Society</i> , page 2191-2196.					
Examiner					Date Considered		
*Examiner: Initial if reference is considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.							

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	AA	4,025,625	05-24-77	Rooney et al.			
	AB	4,196,292	04-01-80	Woltersdorf, Jr. et al.			
	AC	4,087,526	05-02-78	Cragoe, Jr. et al.			
	AD	4,087,542	05-02-78	Cragoe, Jr. et al.			
	AE	4,092,414	05-30-78	Cragoe, Jr. et al.			
	AF	4,100,294	07-11-78	Cragoe, Jr. et al.			
	AG	4,105,769	08-08-78	Rooney et al.			
	AH	4,140,776	02-20-79	Cragoe, Jr. et al.			
	AI	4,145,551	03-20-79	Cragoe, Jr. et al.			
	AJ	4,181,727	01-01-80	Cragoe, Jr. et al.			
	AK	4,237,130	12-02-80	Cragoe, Jr. et al.			
	AL	4,237,144	12-02-80	Cragoe, Jr. et al.			
	AM	4,277,602	07-07-81	Woltersdorf et al.			
	AN	4,291,050	09-22-81	Woltersdorf, Jr. et al.			
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<b>OTHER REFERENCES (Including Author, Title, Date, Pertinent Pages, etc.)</b>							
	AW	Thomas R. Kleyman et al., <u>Amiloride and Its Analogs as Tools in the Study of Ion Transport</u> , <i>The Journal of Membrane Biology</i> , Vol. 105, pages 1-21, 1988.					
	AX	Edward C. Taylor et al., <u>A Facile Route to "Open Chain" Analogues of DDATHE</u> , <i>Heterocycles</i> , Vol. 28, No. 2, 1989.					
	AY	Paul-Michael Windscheif et al., <u>Substituted Dipyrroliethenes and -ethynes and Key Pyridine Building Blocks</u> , <i>Synthesis</i> , pages 87-92, January 1994.					
	AZ	Edward J. Cragoe, Jr., <u>The Synthesis of Amiloride and Its Analogs</u> , page 24-38, Chapter 3.					
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	AA	4,003,927	01-18-77	Woltersdorf, Jr. et al.			
	AB	4,296,122	10-20-81	Cragoe, Jr. et al.			
	AC	4,317,822	03-02-82	Woltersdorf, Jr. et al.			
	AD	4,362,724	12-07-82	Bock et al.			
	AE	4,401,669	08-30-83	Cragoe, Jr. et al.			
	AF	3,974,212	08-10-76	Cragoe, Jr. et al.			
	AG	3,984,465	10-05-76	Cragoe, Jr. et al.			
	AH	3,984,552	10-05-76	Cragoe, Jr. et al.			
	AI	4,067,980	01-10-78	Cragoe, Jr. et al.			
	AJ	4,085,117	04-18-78	Cragoe, Jr. et al.			
	AK	4,085,211	04-18-78	Cragoe, Jr. et al.			
	AL	4,246,406	01-20-81	Cragoe, Jr. et al.			
	AM	3,472,848	10-14-69	Edward J. Cragoe, Jr. et al.			
	AN	3,544,571	12-01-70	Edward J. Cragoe, Jr., et al.			
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	AW	Jack H. Li, et al., <u>Stereoselective Blockage of Amphibian Epithelial Sodium Channels by Amiloride Analogs</u> , <i>The Journal of Pharmacology and Experimental Therapeutics</i> , Vol. 267, No. 3, pages 1081-1084, 1993.					
	AX	Pallav L. Shah, M.D., <u>Chapter 7. Progress in the Treatment of Pulmonary Disease in Cystic Fibrosis</u> , <i>Annual Reports in Medicinal Chemistry</i> , Vol. 36, pages 67-76, 2001.					
	AY	Dieter Worlitzsch et al., <u>Effects of Reduced Mucus Oxygen Concentration in Airway Pseudomonas Infections of Cystic Fibrosis Patients</u> , <i>The Journal of Clinical Investigation</i> , February 2002, Volume 109, Number 3, pages 317-336.					
	AZ	Edward J. Cragoe, Jr., et al., <u>Chapter 7: Diuretic Agents</u> , <i>Annual Reports in Medicinal Chemistry</i> , 1966, page 59-68.					
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	AA	3,991,106	11-09-76	Cragoe, Jr., et al.			
	AB	3,991,087	11-09-76	Cragoe, Jr. et al.			
	AC	3,989,749	11-02-76	Cragoe, Jr. et al.			
	AD	3,987,091	10-19-76	Cragoe, Jr. et al.			
	AE	3,979,361	09-07-76	Schultz et al.			
	AF	3,976,686	08-24-76	Cragoe, Jr. et al.			
	AG	3,976,681	08-24-76	Cragoe, Jr. et al.			
	AH	3,958,004	05-18-76	Cragoe, Jr. et al.			
	AI	3,956,374	05-11-76	Shepard et al.			
	AJ	3,928,624	12-23-75	Cragoe, Jr. et al.			
	AK	3,894,065	07-08-75	Cragoe, Jr. et al.			
	AL	3,668,241	06-06-72	Cragoe, Jr. et al.			
	AM	3,625,950	12-07-71	Edward J. Cragoe, Jr.			
	AN	4,298,743	11-03-81	Cragoe, Jr. et al.			
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	AW	Edward J. Cragoe, Jr., et al., <u>Chapter 7: Diuretic Agents</u> , <i>Annual Reports in Medicinal Chemistry</i> , 1965, page 67-77.					
	AX	Robert L. Smith, et al., <u>Chapter 8: Diuretics</u> , <i>Annual Reports in Medicinal Chemistry</i> , Volume 11, pages 71-79, 1976.					
	AY	Robert L. Smith, et al., <u>Chapter 7: Diuretics</u> , <i>Annual Reports in Medicinal Chemistry</i> , Volume 13, pages 61-70, 1978.					
	AZ	Edward J. Cragoe, Jr., <u>Structure-Activity Relationships in the Amiloride Series</u> , <i>Merck Sharp and Dohme Research Laboratories</i> , 1979, pages 1-20.					
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	AA	3,313,813	04/11/67	Cragoe			
	AB	3,573,306	03/30/71	K.L. Shepared et al.			
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	AW	J. B. BICKING, et al., J. Med. Chem., vol. 8, no. 5, pp. 638-642, "PYRAZINE DIURETICS. I. N-AMIDINO-3-6-HALOPYRAZINECARBOXAMIDES", 1965.					
	AX	R. F. EPAND, et al., British Journal of Cancer, vol. 63, no. 2, pp. 247-251, "REVERSAL OF INTRINSIC MULTIDRUG RESISTANCE IN CHINESE HAMSTER OVARY CELLS BY AMILORIDE ANALOGS", 1991.					
	AY	T. M. COCKS, et al., British Journal of Pharmacology, vol. 95, no. 1, pp. 67-76, 1988.					
	AZ	T. R. KLEYMAN, et al., American Journal of Physiology, vol. 260, no. 2, Pt. 1, pp. C271-C276, 1991.					
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	AW	K. E. BARRETT, et al., Annual Rev. Physiol. vol. 2000, no. 62, pp. 535-572.					
	AX	R.F. Epand, et al., "REVERSAL OF INTRINSIC MULTIDRUG RESISTANCE IN CHINESE HAMSTER OVARY CELLS BY AMILORIDE ANALOGS", Br. J. Cancer (1991), 63, pp. 247-251.					
		Kim E. Barrett, et al., "CHLORIDE SECRETION BY THE INTESTINAL EPITHELIUM: MOLECULAR BASIS AND REGULATORY ASPECTS", Annu. Rev. Physiol. 2000, 62, pp. 535-572.					
	AZ	Copy of Form PCT/IPEA/408, Written Opinion for International Application No. PCT/US03/04817, filed February 19, 2003.					
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